The TECNIS® Multifocal IOL Patient Information Brochure

If you have a cataract, don't worry. You're not alone. Every year, nearly 2,500,000 Americans have cataract surgery. It is one of today's safest and most successful procedures. This brochure is designed to help you and your eye doctor decide on the best type of treatment choice for you. If you have questions about cataract surgery or any of the information in this brochure, please ask your eye doctor.

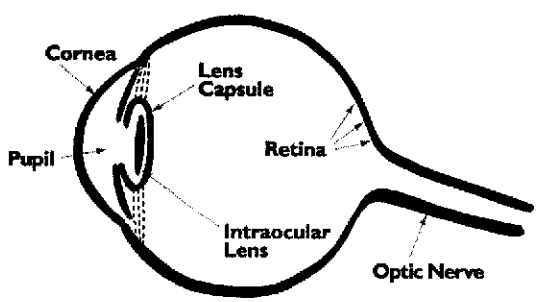
This brochure explains:

- What is a cataract?
- How your eye doctor will treat your cataract
- Choosing the implant best for your vision
- Making the right choice
- What this means to you

What is a cataract?

Inside your eye is a natural lens that helps focus light from outside your eye. The lens creates images in the back of your eye (called the retina) like a camera focuses images on film (Figure 1). As people age, the lens can become less clear, even cloudy. This cloudiness in the lens is called a cataract. Just as a dirty camera lens can spoil a picture, a cataract can prevent light from focusing clearly inside the eye. Typical signs of cataracts are blurred vision and sensitivity to light. For example, you may have trouble reading, or driving at night or at dusk. Colors may seem less vivid and it may be difficult to thread a needle, shave or put on makeup.

Figure 1: Diagram of eye with intraocular lens implant



How your eye doctor will treat your cataract

The most common treatment today is to remove the clouded natural lens and replace it with an artificial lens. The artificial lens is called an ***intraocular lens***, or "IOL". Figure 2 compares the size of the TECNIS® multifocal IOL to a U.S. penny.

Figure 2: Size comparison of TECNIS® multifocal IOL and U.S. penny

When you and your eye doctor agree to proceed with your cataract surgery, you will have a pre-operative evaluation. This includes measuring your eye in order to select the correct lens power.

Cataract surgery is usually done as an outpatient procedure. You will be given anesthesia to numb your eye. Typically, you will be fully awake during the surgery but you will be comfortable and should feel little or no discomfort. To remove the cataract, your surgeon will first make a tiny incision in your eye. Then, a very small probe will be inserted so the cataract can be broken into little pieces. Next, the probe will be used to vacuum out the cataract pieces. Now there will be room for the intraocular lens to be placed in your eye. The surgeon will insert the lens through the same tiny incision. When the surgery is complete, your eye doctor may place a protective patch or shield over your eye. Right after surgery, you should remain in the recovery area for a short time. You should make plans to have someone else drive you home.

After your operation, your eye doctor should give you a wallet card that shows the type of implant in your eye. You should present this card to any eye doctor who examines your eyes after your surgery.

Choosing the implant best for your vision

Your eye doctor has a choice of IOLs that may be used to improve your vision. You may want to discuss with your eye doctor whether a monofocal IOL or multifocal IOL is best for you.

The Monofocal IOL

This type of IOL can give you excellent vision at one distance, usually far. This means that you should see well when you go to a ball game or read distant signs. But you will probably need glasses for tasks requiring near vision, like reading a book or doing crafts.

The TECNIS® Multifocal IOL

The TECNIS® multifocal IOL is made of the same materials and design as many monofocal IOLs. The TECNIS® multifocal IOL will give you good far vision. It can also give you good near vision and useful intermediate vision (at 2 - 5 feet). For example, if you play golf, you may be able to see where your drive lands, sink your putt and write down the score, without wearing glasses. Or when shopping, you may be able to read the aisle signs and the package labels, and count your change, all without glasses. Overall, you may not need to wear your glasses for daily tasks.

Contraindications (When you should not receive this device)

None known.

Risks

As with many things, there may be a trade off. If you decide to have a multifocal lens, your use of glasses may decrease, but at the cost of losing some of the sharpness of your vision. Even with glasses, this loss of sharpness may become worse under poor visibility conditions such as dim light or fog. There may also be some visual side effects such as halos and glare from lights at night that are more common than with a monofocal IOL. Halos are rings of light that you may notice when looking directly at a source of light, such as oncoming car headlights. Glare is a scattered light effect that can appear around a source of light.

General risks with cataract surgery and IOL implantation:

Whatever your lens choice is, there are risks and possible complications of cataract surgery and lens implantation. Complications could be minor or temporary, or could permanently affect your vision. Complications are rare and may include the worsening of your vision, bleeding, or infection. Contact your eye doctor right away if you have any of the following symptoms after surgery: itching, pain, flashing lights/"floaters"/a "curtain" in your vision, redness, severe headache, nausea/vomiting, sensitivity to light or watery eye.

PLEASE NOTE: Warnings and precautions accompany all IOLs because they are prescription-only medical devices. The following warnings and precautions apply to all multifocal IOLs.

Warnings

1. A very small number of patients (less than 1% in U.S. clinical studies) may be dissatisfied and request removal of their multifocal IOL.

2. Under poor visibility conditions, your vision may be reduced more than it would be with a monofocal IOL. Under these conditions, you may have more difficulty recognizing some traffic signs and hard-to-see objects in the road. Therefore, you may need to take extra care when driving, especially in poor light conditions.

3. In rare instances, multifocal IOLs may make some types of retinal surgery more difficult.

Precautions

1. If your eye is not healthy (including glaucoma), your vision may not be good even after your cataract is removed. In this case, you may not get the full benefit of the multifocal IOL. Before surgery, your eye doctor will check to see if you have any eye diseases. Be sure to tell your eye doctor if you have any health conditions that may affect your surgery or vision and provide an updated list of medications to the doctor.

2. There is a chance that your vision with a multifocal IOL may not be good enough to perform very near or detailed "up-close" work without glasses. The Tecnis® multifocal IOL is designed for near vision at approximately 13 inches.

3. Take all prescribed medicines and apply eye drops as instructed.

4. You should avoid any activity that could harm your eye while you are recovering from surgery. Before and after the surgery, your eye doctor will tell you about activity restrictions.

5. If you wear contact lenses, your eye doctor may ask you to discontinue wearing your lenses prior to being evaluated for the multifocal IOL.

6. The multifocal IOL has not been evaluated in patients under the age of 18 years old. As a result, there are insufficient data to support safety and effectiveness of this IOL in this age group.

Making the right choice

Monofocal IOLs and TECNIS® multifocal IOLs have been well studied and are designed to replace the natural lens of the eye. Both have advantages and disadvantages. The following table (Table 1) will help you compare their features. Most of the data shown below represent U.S. study results at 4-6 months after surgery. At that time point, there were 333 patients implanted with the TECNIS® multifocal IOL; of these, 296 patients were implanted in both eyes. There were also 119 patients implanted in both eyes with a monofocal comparison IOL. Some results are presented for vision tests done with both eyes together (binocular vision) as well as one eye alone (monocular vision). Some results from one year after surgery are also presented in two categories. These one-year results are from 116 patients with the TECNIS® multifocal lens implanted in both eyes and 116 patients with the monofocal comparison IOL implanted in both eyes.

Table 1: U.S. Clinical Study Results for the TECNIS® Multifocal IOL and the Monofocal Comparison IOL at 4-6 months

	TECNIS® MULTIFOCAL IOL	**MONOFOCAL IOL**
Far vision (20/40 or better) without glasses	Almost all patients had good distance vision without glasses: 99% with both eyes 93% with one eye	Almost all patients had good distance vision without glasses: 99% with both eyes 98% with one eye
Far vision (20/40 or better) with glasses	Almost all patients had good distance vision with glasses: 100% with both eyes 99% with one eye	All patients had good distance vision with glasses: 100% with both eyes 100% with one eye
Near vision (20/40 or better) without glasses	Almost all patients had good near vision without glasses: 99% with both eyes 96% with one eye	Some patients had good near vision without glasses: 39% with both eyes 17% with one eye

[Table continues on the following page.]

Near vision (20/40 or better) with glasses designed for distance vision	Almost all patients had good near vision when wearing glasses designed for distance vision: 99% with both eyes 97% with one eye	Some patients had good near vision when wearing glasses designed for distance vision: 19% with both eyes 7% with one eye
Combined far and near vision (20/40 or better) without glasses	Almost all patients (98%) had good far and near vision with both eyes at the same time without glasses.	Some patients (21%) had good far and near vision with both eyes at the same time without glasses.
Use of glasses	Percentage of patients reported using glasses: Always 1% Sometimes 11% Never 88%	Percentage of patients reported using glasses: Always 11% Sometimes 84% Never 5%
Use of glasses for far vision	Percentage of patients reported using glasses for distance vision: None of the time 95% Part of the time 4% All of the time 1%	Percentage of patients reported using glasses for distance vision: None of the time 83% Part of the time 8% All of the time 9%
Use of glasses for near vision	Percentage of patients reported using glasses for near vision: None of the time 94% Part of the time 5% All of the time 1%	Percentage of patients reported using glasses for near vision: None of the time 5% Part of the time 64% All of the time 31%
Ability to function at intermediate distances (at 2-5 feet) without glasses	The majority of patients (85%) said they were able to function comfortably at intermediate distances without glasses.	Most patients (95%) said they were able to function comfortably at intermediate distances without glasses.
Quality of overall vision without glasses	Patients gave their overall vision a rating of 8.7 (on a scale of 0 to 10, with 10 being the best)	Patients gave their overall vision a rating of 7.9 (on a scale of 0 to 10, with 10 being the best)

[Table continues on the following page.]

Visual effects [4-6 months and 1 year]	More difficulty with night vision, halos and glare are expected with the multifocal IOL than with a monofocal IOL. At 4-6 months following surgery, more patients reported to their doctors that they experienced halos and glare particularly at nighttime. Most cases were "mild" to "moderate"; however, some were "severe" for halos (9%), night glare (4%), and starbursts (1%). Some patients got used to these effects while others continued to notice them. At one year, severe halos were reported for 5% of patients and severe night glare for 2-3% of patients. In total, severe halos, night glare, or starbursts were reported by 11-12% of patients at 4-6 months. At one year, severe halos, night glare, or starbursts were reported by 7% of patients. In a survey where patients were asked specifically about visual symptoms, patients reported severe difficulty with halos (35%), glare (25%), and night vision (12%) at 4-6 months. At one year, directed reports of severe difficulty with halos (27%), glare (22%), and night vision (8%) decreased. Some patients also experienced blurred vision or had difficulty with vision mostly at intermediate distances (11%). In a few cases (1%), patients requested to have the multifocal lens removed due to difficulty with halos/glare or image quality (blurry/hazy vision).	Some patients reported to their doctors that they experienced halos and glare particularly at nighttime; however, most cases were "mild" to "moderate" with none (0%) being "severe". Some patients also experienced blurred vision or difficulty with vision mostly at near distances (9%). In a survey, some patients (8%) reported difficulty with severe halos at 4-6 months.
Patient satisfaction with the lens [4-6 months and 1 year]	In a survey, patients were asked if they would choose to have the same lens implanted, if they were given a choice. At 4-6 months, most patients (87%) said they would choose this multifocal lens again. At one year, almost all patients (95%) said they would choose this lens again.	In a survey, patients were asked if they would choose to have the same lens implanted, if they were given a choice. At 4-6 months, most patients (85%) said they would choose this monofocal lens again. At one year, even more patients (90%) said they would choose this lens again.

[Table continues on the following page.]

Low contrast vision (driving)	Thirty multifocal and thirty monofocal IOL patients participated in a night-driving simulation substudy. Results indicated that you may have more difficulty distinguishing road signs and hazards as quickly under low-light conditions compared to patients with monofocal IOLs.	In general, under poor visibility conditions, vision with a monofocal IOL may not be as sharp as in good light.

What this means to you

Both the monofocal IOLs and the TECNIS® multifocal IOLs have advantages and disadvantages. To choose an IOL, you should evaluate the factors in the comparison table as they relate to your quality of life. We recommend that you ask your eye doctor to assist in this evaluation.

If you do a lot of night driving in your job or lifestyle, then the TECNIS® multifocal IOL may not be for you. Or, if you wish to minimize halos then you may be happier with a monofocal IOL.

If being less dependent on glasses would make your life better, then the TECNIS® multifocal IOL may be the right choice. For example, if you wish to be able to see well at far, read a newspaper, and have some useful intermediate vision without glasses, then the TECNIS® multifocal IOL may be the better choice. However, you should weigh the possible advantages with the possible disadvantages before deciding.

AMO multifocal IOLs have been well studied in the U.S., Europe, and Japan. In a survey of the U.S. study patients implanted with the TECNIS® multifocal IOL, 87% at 4-6 months and 95% at one year were satisfied with the results of their surgery in the eye implanted with the multifocal IOL and would choose the same lens again if given the chance. Whichever IOL you choose, we hope that you are satisfied and have great pleasure in your improved vision.

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TECNIS® Multifocal Foldable Acrylic Intraocular Lens (IOL)

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

DESCRIPTION: Tecnis® multifocal foldable acrylic intraocular lens, Model ZMA00 is an ultraviolet light-absorbing posterior chamber intraocular lens. It is designed to be positioned posterior to the iris where the lens should replace the optical function of the natural crystalline lens. The Tecnis® multifocal foldable acrylic lens incorporates the squared OptiEdge™ design. The lens is designed to provide both near and distance vision and thereby reduce spectacle dependency. The light distribution between the distance and near focus is approximately 50/50. The labeled power of the lens is the distance power. The near power represents a +4 diopter add in actual lens power. However, accommodation will not be replaced.

INDICATIONS FOR USE: Tecnis® multifocal intraocular lenses are indicated for primary implantation for the visual correction of aphakia in adult patients with and without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire near, intermediate, and distance vision with increased spectacle independence. The intraocular lenses are intended to be placed in the capsular bag.

WARNINGS:

1. Some visual effects associated with multifocal IOLs may be expected because of the superposition of focused and unfocused images. These may include a perception of halos or glare around lights under nighttime conditions. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions. On rare occasions these visual effects may be significant enough that the patient will request removal of the multifocal IOL
2. Under low-contrast conditions, contrast sensitivity is reduced with a multifocal lens compared to a monofocal lens. Therefore, subjects with multifocal lenses should exercise caution when driving at night or in poor visibility conditions.
3. Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the patient's eyesight:
   a. Patients in whom the intraocular lens may interfere with the ability to observe, diagnose or treat posterior segment diseases.
   b. Surgical difficulties at the time of cataract extraction and/or intraocular lens implantation that might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
   c. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
   d. Circumstance that would result in damage to the endothelium during implantation.
   e. Suspected microbial infection.
   f. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.
   g. Congenital bilateral cataracts.
   h. Recurrent severe anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye.
   i. Previous history of, or a predisposition to, retinal detachment.
   j. Patients with only one eye with potentially good vision.
   k. Medically uncontrollable glaucoma.
   l. Corneal endothelial dystrophy.
   m. Proliferative diabetic retinopathy.
4. Because the clinical study was conducted with the lens implanted in the capsular bag, there are insufficient clinical data to demonstrate the safety and effectiveness for placement in the ciliary sulcus.
5. The splitting of the light into more than one focus may affect image quality and lead to some reduction of contrast sensitivity.

6. Well-informed patients with well-defined visual needs and preferences should be selected for Tecnis® multifocal foldable lens implantation. The patients should be informed about the possibility that a decrease in contrast sensitivity and an increase of visual disturbances may affect their ability to drive a car under certain environmental conditions, such as driving at night or in poor visibility conditions.
7. Patients with a predicted postoperative astigmatism greater than 1.0 diopter may not be suitable candidates for multifocal IOL implantation since they may not fully benefit from a multifocal IOL in terms of potential spectacle independence.

PRECAUTIONS:

1. Prior to surgery, the surgeon must inform prospective patients of the possible risks and benefits associated with the use of this device and provide a copy of the patient information brochure to patient.
2. There were no patients under the age of 18 included in the clinical study; therefore there are insufficient clinical data to demonstrate safety and effectiveness in this age group.
3. The central one millimeter area of the Tecnis® multifocal IOL creates a far image focus in accordance with the labeled power of the IOL, so patients with abnormally small pupils (~1mm) should achieve, at a minimum, the prescribed distance vision under photopic conditions; however, because this multifocal design has not been tested in patients with abnormally small pupils, it is unclear whether such patients will derive any near vision benefit.
4. Autorefractors may not provide optimal postoperative refraction of multifocal patients. Manual refraction is strongly recommended.
5. Recent contact lens usage may affect the patient's refraction; therefore in contact lens wearers, surgeons should establish corneal stability without contact lenses prior to determining IOL power.
6. When performing wavefront measurements on a patient with a multifocal lens, two different wavefronts are produced. One wavefront will be in focus (either far or near) and the other wavefront will be out of focus. In this situation, incorrect interpretation of the wavefront measurements is possible.
7. The long-term effects of intraocular lens implantation have not been determined. Therefore the physician should continue to monitor implant patients postoperatively on a regular basis.
8. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. The intraocular pressure of implant patients with glaucoma should be carefully monitored postoperatively.
9. Do not resterilize this intraocular lens by any method.
10. Do not soak or rinse the lens in direct sunlight or at a temperature greater than 50°C (122°F). Do not autoclave the intraocular lens.
11. Do not fold the lens across the loop anchors. The lens should not remain folded for more than 5 minutes.
12. Prior to implanting, examine the lens package for proper lens model, dioptric power, and expiration date.
13. The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is achieved.
14. Care should be taken to achieve centration of the intraocular lens.
15. AMO recommends using The UNFOLDER™ Emerald Series Insertion System to insert the Tecnis® multifocal foldable acrylic lens. Only insertion systems that have been validated and approved for use with this lens should be used. Please refer to the directions for use with the insertion instrument or system for additional information.

CLINICAL STUDY RESULTS for the Silicone Tecnis® Multifocal Lens, Model ZM900

Two clinical studies were conducted in the United States with the silicone version of the Tecnis® multifocal IOL, Model ZM900. The diffractive multifocal optic design of the silicone lens is identical to that of the Tecnis® multifocal acrylic IOL, Model ZMA00. The initial clinical study of the Tecnis® multifocal silicone IOL, Model ZM900 was a one-year, multicenter, evaluator-masked, bilateral, parallel-group comparative clinical evaluation conducted at 13 investigational sites; the second study was a one-year, multicenter, open-label, unilateral or bilateral, expansion study

conducted at 16 investigational sites. Across both studies, a total of 347 Tecnis® ZM900 subjects (306 bilaterally implanted) and 123 monofocal control subjects (122 bilaterally implanted) were enrolled. In the initial study, subjects' lens group assignment was not randomized; each subject was implanted with either Tecnis® multifocal ZM900 lenses or monofocal control lenses according to the subject's preference.

The subject population across both studies consisted of more females than males in both lens groups: 60.8% females in the multifocal lens group and 65.9% in the monofocal lens group. The mean age for multifocal subjects was 65.9 years (ranging from 29 to 87 years); the mean age for monofocal control subjects was slightly older at 68.7 years (ranging from 35 to 84 years). The majority of subjects were Caucasian in both lens groups: 95.7% in the multifocal group and 94.3% in the monofocal group. The remainder of subjects were Black (2.0% in the multifocal group; 5.7% in the monofocal group), Asian (0.9% in the multifocal group; 1.6% in the monofocal group) and "Other" (1.4% in the multifocal group and none in the monofocal group).

The 4-6 month study results are presented for 335 Tecnis® multifocal subjects (297 bilaterally implanted) and 119 bilaterally implanted monofocal subjects). One-year study results are presented for 118 bilateral multifocal subjects and 116 bilateral monofocal subjects; no subjects in the expansion study had reached the one-year visit at the time of data analyses.

Distance Visual Acuities

Photopic (85 cd/m^2) distance visual acuity results for both lens groups are presented in **Tables 1-4**. **Tables 1** and **2** present monocular uncorrected and best corrected distance visual acuity results for subjects' first eyes at 4-6 months and one year, respectively. **Table 3** shows binocular results at 4-6 months. At both 4-6 months and one year, monocular best corrected distance visual acuity results for Tecnis® ZM900 first eyes were above the FDA grid rates for safety (92.5%; **Tables 1** and **2**). Additionally, all best case Tecnis® ZM900 first eyes (100%, 327/327 at 4-6 months and 113/113 at one year) achieved 20/40 or better best corrected distance visual acuity exceeding the FDA grid rate for best case (96.7%) as well.

Table 1: Monocular Distance Visual Acuity at 4-6 Months

Visual Acuity	Tecnis ZM900 N=333		Monofocal Control N=119	
	Uncorrected	Best Corrected	Uncorrected	Best Corrected
20/20 or better	31.2%	75.1%	39.5%	82.4%
20/25 or better	62.2%	94.3%	68.9%	94.1%
20/32 or better	82.6%	98.2%	90.8%	99.2%
20/40 or better	92.8%	99.7%	97.5%	100.0%
20/50 – 20/80	6.9%	0.3%	2.5%	0.0%
20/100 or worse	0.3%	0.0%	0.0%	0.0%

Table 2: Monocular Distance Visual Acuity at One Year

Visual Acuity	Tecnis ZM900 N=116		Monofocal Control N=114	
	Uncorrected	Best Corrected	Uncorrected	Best Corrected
20/20 or better	26.7%	69.8%	49.1%	84.2%
20/25 or better	60.3%	93.1%	77.2%	93.9%
20/32 or better	81.0%	99.1%	86.8%	100.0%
20/40 or better	91.4%	100.0%	97.4%	100.0%
20/50 – 20/80	6.9%	0.0%	2.6%	0.0%
20/100 or worse	1.7%	0.0%	0.0%	0.0%

Table 3: Binocular Distance Visual Acuity at 4-6 Months

Visual Acuity	Tecnis ZM900 N=294		Monofocal Control N=119	
	Uncorrected	Best Corrected	Uncorrected	Best Corrected
20/20 or better	56.1%	84.7%	75.6%	87.4%
20/25 or better	83.3%	98.0%	91.6%	98.3%
20/32 or better	95.9%	100.0%	98.3%	100.0%
20/40 or better	98.6%	100.0%	99.2%	100.0%
20/50 – 20/80	1.4%	0.0%	0.8%	0.0%
20/100 or worse	0.0%	0.0%	0.0%	0.0%

Mean monocular and binocular distance visual acuities for both lens groups are presented in **Table 4**. Mean distance visual acuities were clinically comparable between lens groups with mean differences between lens groups within one line or less. The lower limits of the confidence intervals of the mean differences between groups were one line or less for uncorrected distance visual acuities and approximately one-half line or less for best corrected distance visual acuities, demonstrating non-inferiority of the Tecnis® ZM900 lens for distance visual acuity compared to the monofocal control.

Table 4: Mean Distance Visual Acuities

Distance Visual Acuity	Time point	Lens Group	Monocular			Binocular		
			N	Mean Snellen Equivalent	Mean Diff. (ETDRS lines)	N	Mean Snellen Equivalent	Mean Diff. (ETDRS lines)
Uncorrected	4-6 Months	ZM900	333	20/27	-0.38	294	20/22	-0.50
		Monofocal	119	20/25		119	20/20	
	1 Year	ZM900	116	20/28	-0.68	114	20/22	-0.45
		Monofocal	114	20/24		114	20/20	
Best Corrected	4-6 Months	ZM900	333	20/20	-0.25	294	20/18	-0.21
		Monofocal	119	20/19		119	20/17	
	1 Year	ZM900	116	20/21	-0.30	114	20/18	-0.33
		Monofocal	114	20/19		114	20/17	

Near Visual Acuities Near visual acuities were tested at the fixed test distance of 33 cm and at the subjects' preferred or "best" test distance, with and without distance correction, under both photopic (85 cd/m^2) and mesopic (3 cd/m^2) lighting conditions. Mean monocular and binocular near visual acuities at 4-6 months for both lens groups are presented in **Table 5.** All mean near visual acuities were significantly better ($p<0.0001$) for multifocal subjects compared to monofocal subjects by approximately four or more lines of acuity. Near visual acuity results demonstrate the effectiveness of the Tecnis® multifocal lens in providing substantial near vision compared to the monofocal control lens.

Table 5: Mean Near Visual Acuities at 4-6 Months

Near Visual Acuity	Test Distance	Lens Group	Monocular N	Monocular Mean Snellen Equivalent	Monocular Diff. in Means (ETDRS lines)	Binocular N	Binocular Mean Snellen Equivalent	Binocular Diff. in Means (ETDRS lines)
Uncorrected Photopic	33 cm	ZM900	333	20/30*	4.3	294	20/25*	4.0
		Monofocal	119	20/81		119	20/65	
	Best	ZM900	332	20/28*	4.0	292	20/23*	3.6
		Monofocal	119	20/69		119	20/53	
Distance Corrected Photopic	33 cm	ZM900	332	20/28*	4.9	294	20/24*	4.6
		Monofocal	119	20/86		119	20/69	
	Best	ZM900	331	20/26*	4.6	291	20/23*	4.5
		Monofocal	119	20/76		119	20/64	
Distance Corrected Mesopic	33 cm	ZM900	332	20/45*	4.8	294	20/37*	4.7
		Monofocal	119	20/134		119	20/111	
	Best	ZM900	330	20/42*	4.7	291	20/35*	4.7
		Monofocal	119	20/123		119	20/104	

*Statistically significant difference in mean ETDRS scores versus monofocal control ($p<0.0001$)

Mean best test distances for multifocal subjects were close to the theoretical value of 33.0 cm both monocularly and binocularly, with and without distance correction in place. Mean best test distances for monofocal subjects were, on average, 2-3 cm greater than the means for multifocal subjects.

Distributions of near visual acuity results for both lens groups are presented in **Tables 6-8**. **Tables 6** and **7** present 4-6 month and one-year results, respectively, for first-eye monocular photopic uncorrected and distance corrected near visual acuities. **Table 8** presents 4-6 month results for binocular photopic uncorrected and distance corrected near visual acuities. In all cases, much larger proportions of multifocal subjects achieved better near visual acuities compared to monofocal subjects, with or without correction, monocularly or binocularly, at the fixed text distance of 33 cm or at the subject's preferred test distance. The true test of a multifocal optic is the evaluation of near vision with distance correction in place eliminating any effects from residual refractive error. With distance correction in place, 97-99% of Tecnis® ZM900 subjects achieved 20/40 or better at near at best distance, monocularly or binocularly, compared to 7-19% of monofocal subjects (**Tables 6-8**).

Table 6: Monocular Photopic Uncorrected and Distance Corrected Near Visual Acuity at 4-6 Months

	Uncorrected				Distance Corrected			
	Tecnis ZM900		Monofocal		Tecnis ZM900		Monofocal	
Near Visual Acuity	33 cm N=333	Best N=332	33 cm N=119	Best N=119	33 cm N=332	Best N=331	33 cm N=119	Best N=119
20/20 or better	17.1%	26.2%	0.0%	0.0%	22.3%	31.4%	0.0%	0.0%
20/25 or better	44.4%	56.3%	1.7%	3.4%	56.0%	64.4%	0.0%	0.0%
20/32 or better	76.0%	85.8%	2.5%	7.6%	84.9%	89.1%	1.7%	3.4%
20/40 or better	91.0%	95.8%	7.6%	16.8%	94.9%	97.0%	5.0%	6.7%
20/50 – 20/80	8.4%	4.2%	49.6%	53.8%	4.5%	2.7%	43.7%	56.3%
20/100 or worse	0.6%	0.0%	42.9%	29.4%	0.6%	0.3%	51.3%	37.0%

Table 7: Monocular Photopic Uncorrected and Distance Corrected Near Visual Acuity at One Year

	Uncorrected				Distance Corrected			
	Tecnis ZM900		Monofocal		Tecnis ZM900		Monofocal	
Near Visual Acuity	33 cm N=116	Best N=116	33 cm N=113	Best N=113	33 cm N=116	Best N=116	33 cm N=113	Best N=113
20/20 or better	16.4%	27.6%	0.0%	0.0%	24.1%	34.5%	0.0%	0.0%
20/25 or better	37.1%	47.4%	0.9%	1.8%	53.4%	66.4%	0.0%	0.9%
20/32 or better	69.8%	75.9%	2.7%	5.3%	79.3%	81.9%	2.7%	4.4%
20/40 or better	83.6%	90.5%	6.2%	14.2%	95.7%	97.4%	6.2%	10.6%
20/50 – 20/80	14.7%	9.5%	46.0%	45.1%	4.3%	2.6%	42.5%	43.4%
20/100 or worse	1.7%	0.0%	47.8%	40.7%	0.0%	0.0%	51.3%	46.0%

Table 8: Binocular Photopic Uncorrected and Distance Corrected Near Visual Acuity at 4-6 Months

	Uncorrected				Distance Corrected			
	Tecnis ZM900		Monofocal		Tecnis ZM900		Monofocal	
Near Visual Acuity	33 cm N=294	Best N=292	33 cm N=119	Best N=119	33 cm N=294	Best N=291	33 cm N=119	Best N=119
20/20 or better	33.3%	45.9%	0.0%	0.8%	42.9%	49.8%	0.0%	0.0%
20/25 or better	75.5%	82.2%	1.7%	6.7%	79.6%	84.9%	0.0%	0.8%
20/32 or better	94.9%	96.6%	7.6%	17.6%	96.3%	97.3%	5.0%	8.4%
20/40 or better	99.0%	99.0%	21.0%	38.7%	98.3%	98.6%	13.4%	18.5%
20/50 – 20/80	0.7%	0.7%	63.9%	52.9%	1.7%	1.4%	59.7%	60.5%
20/100 or worse	0.3%	0.3%	15.1%	8.4%	0.0%	0.0%	26.9%	21.0%

Combination Visual Acuities

Combination visual acuities represent the proportion of subjects that achieved a specific distance acuity and a specific near acuity at the same visit. **Figures 1 and 2** present combined uncorrected distance and near (tested at 33 cm) visual acuities for binocular subjects at 4-6 months. **Figure 1** presents the proportions of subjects that achieved 20/40 or better both at distance and near for both lens groups; **Figure 2** presents the proportions of subjects that achieved 20/25 or better distance and 20/32 or better near for both lens groups. In both comparisons, significantly more multifocal subjects ($p<0.0001$) achieved the combined visual acuities compared to monofocal subjects with or without distance correction. The best test of multifocal optic performance is the evaluation of simultaneous good distance and near acuity with distance correction in place eliminating any effect from residual refractive error; with distance correction in place, 94% of Tecnis® ZM900 subjects achieved 20/25 or better distance and 20/32 or better near visual acuity compared to only 5.0% of monofocal subjects (**Figure 2**).

Figure 1:
Combined 20/40 or Better Binocular Distance and Near Photopic Visual Acuity at 4-6 Months

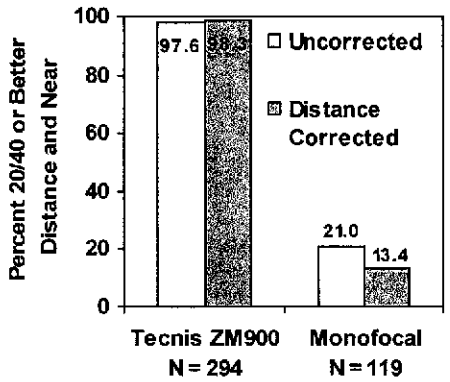
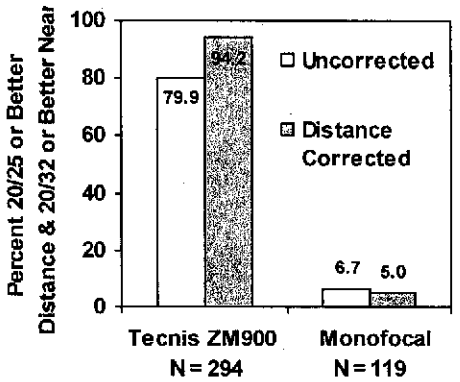


Figure 2:
Combined 20/25 or Better Binocular Distance and 20/32 or Better Binocular Near Photopic Visual Acuity at 4-6 Months



Reading Ability

Binocular reading acuity and speed were evaluated in the initial study under photopic lighting conditions at the subject's best distance using the MNRead chart. **Table 9** presents the results for both lens groups at one year. Statistically significant differences in mean binocular reading acuity ($p<0.0001^a$), critical print size ($p<0.0001^a$) and maximum reading speed ($p=0.0007^a$) were found between lens groups with multifocal subjects having better reading acuity, smaller critical print size (smallest print a subject can read near their maximum reading speed) and faster reading speed. Critical print size results indicate that on average, multifocal subjects were able to read near their maximum reading speed at three lines better than monofocal control subjects.

Table 9
Mean Binocular Distance Corrected Reading Acuity and Speed at One Year

Lens Group	N	Reading Acuity		Reading Speed	
		Mean Snellen Equivalent	Mean Test Distance (cm)	Mean Critical Print Size Snellen Equivalent	Mean Words Per Minute
ZM900	114	20*	34.4*	30*	148*
Monofocal	113	47	41.1	63	117

* Statistically significant difference vs. monofocal control

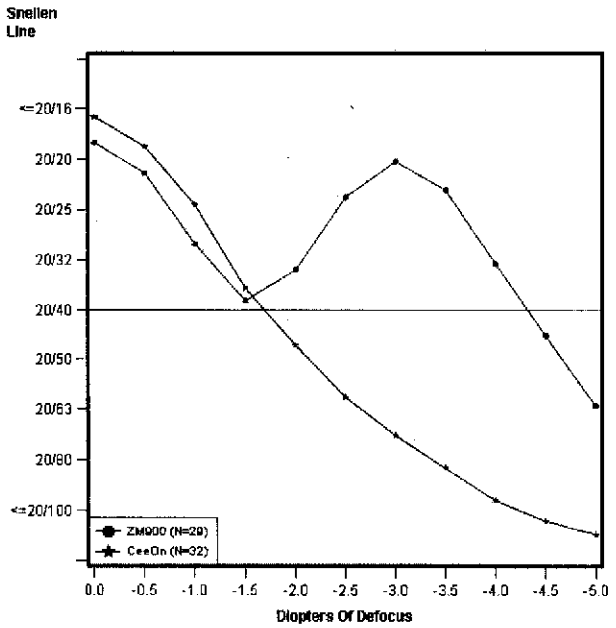
Depth of Focus

Defocus curve testing was performed on a subset of 30 subjects from each lens group at the 4-6 month study exam in the initial study to evaluate binocular best corrected distance visual acuity defocus curves, and any effects of pupil size. The substudy was a non-randomized, parallel-group comparison of the binocular best corrected visual acuity depth of focus at three pupil size ranges: ≤2.5 mm; >2.5 mm and <4.0 mm; and ≥4.0 mm.

Multifocal subjects were found to have a significantly increased measured depth of focus compared to monofocal subjects overall (**Figure 3**) with a prominent near peak around -3.0 D essentially equivalent to the distance peak or plano refraction.

[a] P-value was not adjusted for multiplicity.

Figure 3
Mean Visual Acuity at Each Defocus Level for All Subjects at Their Natural Pupil Size



The depth of focus performance for the Tecnis® multifocal IOL strongly illustrates the multifocality of the optic design at any pupil size (**Figure 4**). Minimal pupil size effect was observed. Even at intermediate distances (~1.5 D of defocus), depth of focus curves for all pupil size groups were generally 20/40 or better indicating a large range of functional vision. In summary, depth of focus was significantly increased for multifocal subjects compared to monofocal subjects with a substantial near peak evident for multifocal subjects for all pupil size groups.

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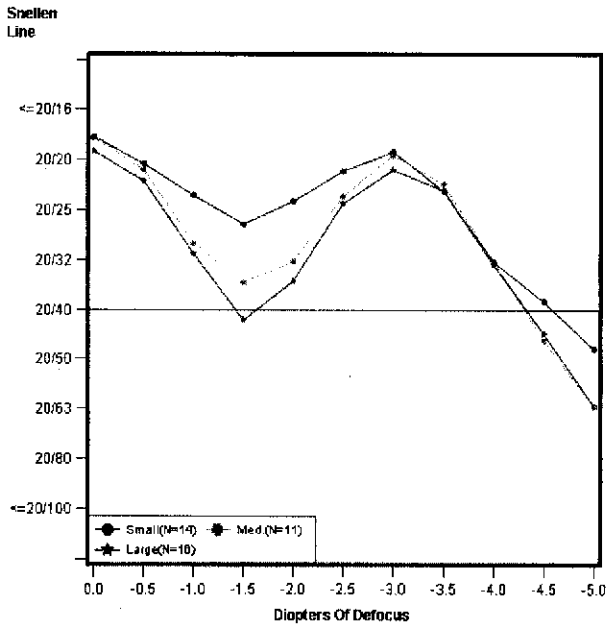
Figure 4

Mean Visual Acuity at Each Defocus Level for Tecnis Multifocal Subjects by Pupil Size Groups: Small: ≤2.5 mm; Medium: >2.5 mm, <4.0 mm; Large: ≥4.0 mm



Contrast Sensitivity

Binocular best corrected distance contrast sensitivity testing was performed on subjects in the initial study at the 4-6 month study exam under three lighting conditions: mesopic with glare, mesopic without glare, and photopic with glare. Testing was performed using the Functional Acuity Contrast Test (FACT) sine wave grating charts with the Optec 6500 Vision Tester.

Mean contrast scores for the multifocal group were less than that for the monofocal IOL group under each lighting condition and spatial frequency (**Table 10**). Mean differences between IOL groups ranged between 0.10 to 0.26 log units, with the majority under 0.20 log units. Except in one case, the lower limits of the confidence intervals of the mean differences did not exceed 0.30 log units. When results were analyzed by pupil size, no noticeable pupil size effects were found for either lens group under any lighting condition.

Table 10
Mean Best Case Binocular Log Contrast Sensitivity Scores at 4-6 Months

Spatial Frequency	Lens Model	N	Mesopic Without Glare	Mesopic With Glare	Photopic With Glare
1.5 cpd	ZM900	110	1.54	1.25	Not tested
	Monofocal	109	1.64	1.36	Not tested
3.0 cpd	ZM900	110	1.63	1.29	1.60
	Monofocal	109	1.75	1.50	1.75
6.0 cpd	ZM900	110	1.56	1.23	1.64
	Monofocal	109	1.70	1.49	1.80
12.0 cpd	ZM900	110	0.95	0.85	1.23
	Monofocal	109	1.14	0.99	1.43
18.0 cpd	ZM900	110	Not tested	Not tested	0.77
	Monofocal	109	Not tested	Not tested	0.96

Driving Performance

A night driving performance substudy was conducted to assess functional performance differences between multifocal and monofocal IOL subjects in the initial study. Binocular visual

performance was measured while driving under low visibility conditions such as night driving and with headlight glare conditions. The Night Driving Simulator developed and validated by Vision Sciences Research Corporation (VSRC) was used to measure night driving visibility distances and evaluate driving safety in terms of critical stopping sight distance. Driving simulation substudy results are presented for 26 multifocal subjects and 31 monofocal subjects.

The Night Driving Simulator included two driving scenes, a nighttime rural road and a nighttime city street. Six visual test targets were used: two different road warning signs, two text signs and two road hazards. The size and content of the signs and hazards varied requiring different detection and identification distances. The simulated visibility conditions for nighttime driving in rural and city roads were clear weather, inclement weather (fog), and glare conditions.

The night driving visibility results are presented in **Tables 11** and **12** for the rural road and in **Tables 13** and **14** for the city street. In general, mean night driving visibility distances for detection and identification of text, warning and pedestrian targets was lower for multifocal subjects than for monofocal subjects. However, the mean percent loss in visibility detection and identification distances for Tecnis® multifocal subjects compared to the monofocal control group was within 25% loss for most distances, even in city roads with visual clutter and background interaction.

Table 11
Visibility Distance and Time for Rural Detection

Visibility Condition	Target	Mean Visibility Distance (feet)		Difference (feet)	Mean % Loss	Mean Visibility Time (sec)	
		ZM900	Monofocal			ZM900	Monofocal
Normal	Text	715 ± 33	734 ± 19	19	2.6%	8.86	9.09
	Warning	668 ± 36	703 ± 29	35	5.0%	8.28	8.72
	Pedestrian	630 ± 39	667 ± 22	37	5.6%	7.81	8.27
Fog	Text	690 ± 32	709 ± 23	19	2.7%	8.55	8.79
	Warning	623 ± 32	658 ± 29	35	5.3%	7.73	8.16
	Pedestrian	616 ± 31	642 ± 38	26	4.1%	7.64	7.96
Glare	Text	645 ± 35	678 ± 28	33	4.8%	8.00	8.41
	Warning	591 ± 34	635 ± 27	44	6.9%	7.32	7.87
	Pedestrian	546 ± 75	621 ± 39	75	12.0%	6.77	7.70

Table 12
Visibility Distance and Time for Rural Identification

Visibility Condition	Target	Mean Visibility Distance (feet)		Difference (feet)	Mean % Loss	Mean Visibility Time (sec)	
		ZM900	Monofocal			ZM900	Monofocal
Normal	Text	353 ± 85	479 ± 76	126	26.3%	4.38	5.94
	Warning	502 ± 70	583 ± 40	81	14.0%	6.22	7.23
	Pedestrian	455 ± 103	583 ± 67	128	21.9%	5.64	7.23
Fog	Text	281 ± 73	393 ± 65	112	28.5%	3.48	4.87
	Warning	426 ± 75	529 ± 69	103	19.5%	5.28	6.56
	Pedestrian	387 ± 109	495 ± 96	108	21.7%	4.80	6.14
Glare	Text	253 ± 82	392 ± 67	139	35.6%	3.13	4.86
	Warning	396 ± 95	526 ± 59	130	24.7%	4.90	6.52
	Pedestrian	335 ± 111	465 ± 91	130	27.9%	4.16	5.76

Table 13
Visibility Distance and Time for City Detection

Visibility Condition	Target	Mean Visibility Distance (feet)		Difference (feet)	Mean % Loss	Mean Visibility Time (sec)	
		ZM900	Monofocal			ZM900	Monofocal
Normal	Text	279 ± 37	333 ± 44	54	16.2%	5.43	6.48
	Warning	297 ± 31	320 ± 32	23	7.1%	5.79	6.23
	Pedestrian	348 ± 89	358 ± 92	10	2.6%	6.78	6.97
Fog	Text	255 ± 49	300 ± 41	45	15.0%	4.97	5.85
	Warning	276 ± 28	303 ± 30	27	9.0%	5.37	5.90
	Pedestrian	326 ± 80	358 ± 88	32	8.9%	6.36	6.98
Glare	Text	229 ± 42	279 ± 32	50	17.8%	4.46	5.43
	Warning	266 ± 32	295 ± 32	29	9.9%	5.17	5.74
	Pedestrian	291 ± 69	326 ± 82	35	10.7%	5.66	6.35

Table 14
Visibility Distance and Time for City Identification

Visibility Condition	Target	Mean Visibility Distance (feet)		Difference (feet)	Mean % Loss	Mean Visibility Time (sec)	
		ZM900	Monofocal			ZM900	Monofocal
Normal	Text	255 ± 30	312 ± 37	57	18.3%	4.96	6.07
	Warning	293 ± 33	320 ± 32	27	8.4%	5.70	6.23
	Pedestrian	324 ± 72	348 ± 82	24	7.1%	6.31	6.79
Fog	Text	219 ± 40	273 ± 32	54	19.7%	4.27	5.32
	Warning	269 ± 32	300 ± 30	31	10.2%	5.25	5.85
	Pedestrian	305 ± 65	343 ± 71	38	11.0%	5.95	6.68
Glare	Text	199 ± 57	263 ± 39	64	24.3%	3.88	5.12
	Warning	261 ± 35	293 ± 31	32	11.1%	5.08	5.71
	Pedestrian	276 ± 53	310 ± 65	34	10.9%	5.38	6.04

Fundus Visualization
At the 4-6 month study visit, investigators evaluated the ability to visualize the fundus during the dilated fundus exams. In all cases (100%; 333/333 multifocal first eyes and 119/119 monofocal first eyes), fundus visualization was deemed "adequate". During the studies, no difficulties were reported in evaluating or treating retinal complications in multifocal eyes; however, only one multifocal eye underwent a surgical retinal procedure.

Subject Satisfaction/Quality of Life Evaluation
Two subjective questionnaires were administered to subjects to assess the impact of the lens on vision-related quality of life: a sponsor-developed questionnaire collected information regarding visual quality and subject satisfaction, and the Modified TyPE Specification for Cataracts (developed by Jonathan Javitt, M.D., M.P.H., in 1994) measured multifocal-specific quality of life impact information. The questionnaires were administered via telephone by masked, trained interviewers following the clinical study exams preoperatively, at 4-6 months and one year.

Figures 5-7 present the frequency of spectacle wear for bilaterally implanted monofocal subjects at 4-6 months. Spectacle independence rates for the Tecnis® ZM900 lens group were statistically higher than the monofocal control group for overall, distance and near spectacle use ($p<0.0001^a$). Similar statistically significant results were noted at one year as well.

[a] P-value was not adjusted for multiplicity.

Figure 5:
Spectacle Usage for Bilateral Subjects at 4-6 Months

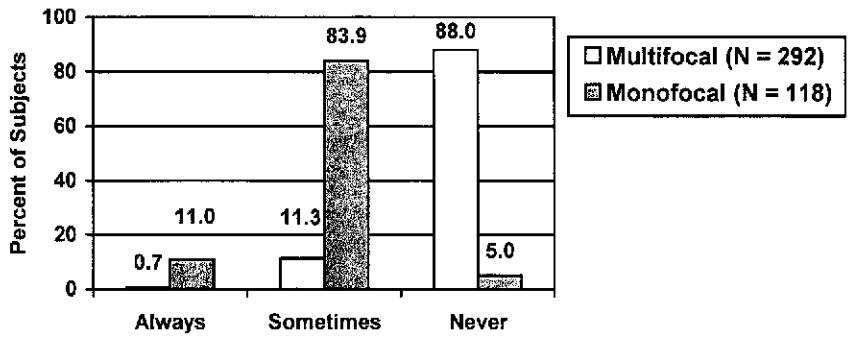


Figure 6:
Spectacle Usage for Distance Vision for Bilateral Subjects at 4-6 Months

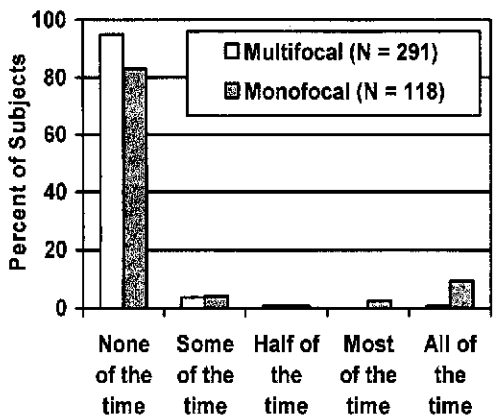


Figure 7:
Spectacle Usage for Near Vision for Bilateral Subjects at 4-6 Months

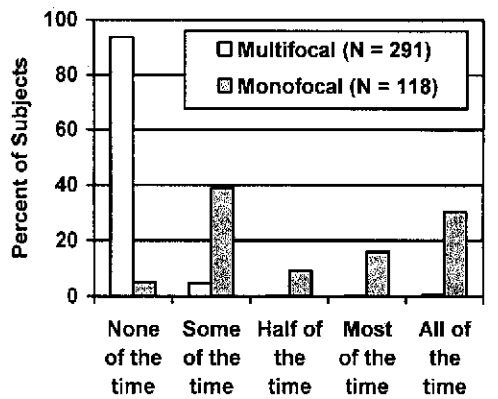


Table 15 presents subjects' ability to function comfortably without glasses. Statistically significant differences were found between lens groups ($p<0.0001$[a]) with more multifocal subjects reporting the ability to function comfortably at near without glasses at both 4-6 months and one year.

Table 15
Ability to Function Comfortably Without Glasses for Bilateral Subjects

Ability to Function Comfortably at:	4-6 Months		One Year	
	Tecnis ZM900 N=292	Monofocal N=118	Tecnis ZM900 N=112	Monofocal N=115
Near	94.2%*	16.9%	96.4%*	30.4%
Intermediate	85.3%	94.9%	93.8%	84.2%
Distance	90.4%	94.9%	96.4%	98.3%

* Statistically significant difference vs. monofocal control

Satisfaction of vision without glasses (**Table 16**) was assessed on a scale of 1-5, with 1 being "not at all satisfied" and 5 being "completely satisfied". At both 4-6 months and one year, statistically significant differences were found between lens groups for overall ($p\leq0.0052$[a]) and

[a] P-value was not adjusted for multiplicity.

during the day ($p<0.0001$[a]) with mean ratings for multifocal subjects closer to "completely satisfied" and mean ratings for monofocal subjects closer to "mostly satisfied". At night, there were no statistically significant differences between lens groups with mean ratings for both lens groups "mostly satisfied" or better.

Table 16
Mean Rating of Satisfaction With Vision Without Glasses for Bilateral Subjects
(on a scale of 1-5, with 5 being best)

Satisfaction With Vision	4-6 Months		One Year	
	Tecnis ZM900 N=292	Monofocal N=118	Tecnis ZM900 N=112	Monofocal N=115
Overall	4.46*	4.20	4.59*	4.25
During the day	4.53*	4.19	4.65*	4.24
At Night	4.09	4.11	4.37	4.19

* Statistically significant difference vs. monofocal control

Subjects also rated the degree of trouble with vision without glasses in the day and at night (**Table 17**) on a scale of 1 to 5, with 1 being "no trouble at all" and 5 being "major or overwhelming trouble". At both 4-6 months and one year, significant differences were found in favor of the Tecnis® ZM900 lens group ($p<0.0001$[a]) during the day with lower mean trouble ratings. At night, a significant difference ($p=0.0047$[a]) was noted in favor of the multifocal lens at one year. However, postoperative scores for both lens groups were generally low with mean ratings between "no trouble" and "a little bit of trouble".

Table 17
Mean Rating of Trouble With Vision Without Glasses for Bilateral Subjects
(on a scale of 1-5, with 5 being worst)
Directed Responses to a Prompted Choice Questionnaire

Trouble With Vision	4-6 Months		One Year	
	Tecnis ZM900 N=292	Monofocal N=118	Tecnis ZM900 N=112	Monofocal N=115
During the day	1.44*	1.80	1.23*	1.86
At night	1.97	1.89	1.63*	2.00

* Statistically significant difference vs. monofocal control

Subjects also rated their vision in general without glasses (**Table 18**) on a scale of 0 to 10, with zero being "worst possible vision" and 10 being "best possible vision". At both 4-6 months and one year, multifocal subjects rated their vision as significantly better than monofocal subjects overall ($p<0.0001$[a]).

Table 18
Mean Rating of Vision Without Glasses for Bilateral Subjects
(on a scale of 0-10, with 10 being best)

Rating of Vision	Tecnis ZM900		Monofocal	
	N	Mean Rating	N	Mean Rating
4-6 Months	292	8.67*	118	7.94
One Year	112	8.94*	115	7.86

* Statistically significant difference vs. monofocal control

Subjects were asked about their desire to elect the same IOL again, if given the opportunity. As shown in **Table 19**, at both 4-6 months and one year, more multifocal subjects indicated they would elect the IOL again compared to monofocal subjects, although the difference was not statistically significant. The primary reasons subjects would not elect the IOL again were

[a] P-value was not adjusted for multiplicity.

dissatisfaction with visual outcomes for both lens groups as well as optical/visual effects for the multifocal subjects and the need for glasses for monofocal subjects.

Table 19
Desire to Elect IOL Again for Bilateral Subjects
Directed Response to a Prompted Choice Questionnaire

	Tecnis ZM900				Monofocal			
	4-6 Months N = 292		One Year N = 112		4-6 Months N = 118		One Year N = 115	
Elect IOL Again?	n	%	n	%	n	%	n	%
Yes	255	87.3	106	94.6	100	84.7	103	89.6
No	30	10.3	5	4.5	15	12.7	12	10.4
Undecided	7	2.4	1	0.9	3	2.5	0	0.0

Adverse Events

The incidence of cumulative adverse events for the Tecnis® ZM900 multifocal first eyes compared to the US FDA historical grid are presented in **Table 20**. The incidence rates for the Tecnis® ZM900 lens compared favorably to the specified FDA rates. Only the rate of surgical re-interventions in the Tecnis® ZM900 lens group was statistically higher than the FDA grid rate of 0.8% ($p<0.0001$)However, the observed proportion of lens-related surgical re-interventions in first eyes is not statistically higher than the FDA grid rate ($p=0.575$) with only three subjects out of 348 experiencing such events (3/348; 0.9%). A third subject also experienced a lens-related surgical re-intervention in a second eye (due to halos/glare); however, the rate for second eye lens-related surgical re-interventions was also not statistically above the grid rate ($p=0.4432$). The rate of non-lens-related surgical re-interventions was statistically higher than the grid rate for multifocal first eyes ($p=0.0022$). Secondary surgical re-intervention events for multifocal first eyes are specified in **Table 21**.

Table 20
Cumulative Adverse Events for Tecnis ZM900 First Eyes

Cumulative Adverse Event	ZM900 N=348*		FDA Grid Rate
	n	%	%
Hyphema	0	0.0	2.2
Macular edema	8	2.3	3.0
Retinal detachment	0	0.0	0.3
Pupillary block	0	0.0	0.1
Lens dislocation	0	0.0	0.1
Endophthalmitis	1#	0.3	0.1
Hypopyon	1#	0.3	0.3
Surgical re-intervention	12	3.4	
Lens-related	2Ω	0.6	0.8
Not lens-related	10#	2.9	

* Excluded subject with lens exchange due to incorrect lens type included in study population for adverse events only: 348 first eyes instead of 347.

\# One eye experienced endophthalmitis and hypopyon followed by non-lens-related surgical re-interventions (trabeculectomy and two filtration bleb revisions).

Ω Following study completion, two subjects experienced lens-related events in the first eye; however, one of these had also experienced an event in the first eye during the study. Therefore, the total number of first eyes with lens-related events during and after the study is three (3/348; 0.9%) – the same three subjects with lens-related events in second eyes during the study.

Table 21
Surgical Re-Interventions in Tecnis ZM900 First Eyes

Surgical Re-Interventions	Tecnis ZM900 N=348*	
	n	%
Lens-Related	**2**	**0.6%**
Lens removal due to halos/glare	1†Δ	0.3
Lens repositioning (image quality: blurry/hazy vision)	1‡	0.3
Not Lens-Related	**10**	**2.9%**
Iris prolapse/wound repair	1	0.3
Lens exchange: - Lens power (refractive error)	3	0.9
- Incorrect lens type	1*	0.3
Macular hole repair	1	0.3
Vitrectomy/membrane peel for macular pucker	1	0.3
Trabeculectomy and two subsequent filtration bleb revisions	1¥	0.3
Treatment injections for cystoid macular edema	2	0.6
TOTAL EYES	**12***	**3.4%**

* Includes excluded subject (lens exchange following implantation of non-study IOL) for adverse events only
† This subject also experienced a pupilloplasty and lens removal in the second eye due to halos and glare
Δ This subject eventually underwent lens removal in both eyes due to halos and glare
‡ This subject eventually underwent lens removal in both eyes due to image quality (blurry/hazy vision)
¥ Subsequent to endophthalmitis and hypopyon

Medical complications at 4-6 months and one year (persistent) are presented for Tecnis® ZM900 first eyes in **Table 22**. There was only one persistent event; one first eye unilateral subject was diagnosed with secondary glaucoma/raised intraocular pressure (IOP) requiring treatment beginning approximately five months postoperatively through the one-year study timeframe. The rate for raised IOP requiring treatment at one year was not statistically higher than the FDA grid rate (p=0.3743). Some medical complications were reported at 4-6 months, however, none of the rates were statistically higher than the one-year grid rates.

Table 22
Medical Complications and Adverse Events for Tecnis ZM900 First Eyes at 4-6 Months and One Year (Persistent)

Persistent Adverse Event	ZM900				FDA Grid Rate
	4-6 Months N=333		One Year N=116		
	n	%	n	%	%
Macular edema	1	0.3	0	0.0	0.5
Corneal edema	1	0.3	0	0.0	0.3
Iritis	2	0.6	0	0.0	0.3
Raised IOP requiring treatment	1#	0.3	1#	1.0	0.4

Same eye

Optical/Visual Symptoms

Non-directed subject responses were obtained from the open-ended question "Are you having any difficulties with your eyes or vision" as asked at the clinical study exams. **Table 23** presents the incidence of non-directed responses for optical/visual symptoms for first eyes in both lens groups at 4-6 months and one year postoperatively. The most reported optical/visual symptoms noted in the Tecnis® multifocal lens group were halos, with most reports being "mild" to "moderate". For monofocal first eyes, halos were also reported but with lower incidence and severity. Blurred/difficulty with vision was reported frequently in both lens groups; the majority of reports in the multifocal group were noted for intermediate distances whereas the majority of reports in the monofocal group were noted at near. Night glare and starbursts were reported with higher frequencies in the multifocal group; however, most reports were noted as "mild" to "moderate". Lower rates were reported at the one-year visit compared to earlier study time points.

Across both studies, three multifocal subjects (0.9%) underwent study lens removal; two resulting from halos/glare and one from dissatisfaction with image quality (blurry/hazy vision).

Table 23
Optical/Visual Symptoms* Pertaining to Visual Disturbances and Image Quality for First Eyes, Non-directed Responses at 4-6 Months and One Year

Optical/Visual Symptoms	Tecnis ZM900		Monofocal Control	
	4-6 Months N=333	One Year N=116	4-6 Months N=119	One Year N=116
Visual Disturbances				
Day glare	3.9%	5.2%	1.7%	1.7%
Floaters	4.2%	5.2%	4.2%	2.6%
Halos#	40.8% Mild = 16.5% Moderate = 15.3% Severe = 9.0%	22.4% Mild = 12.1% Moderate = 5.2% Severe = 5.2%	4.2% Mild = 2.5% Moderate = 1.7%	8.6% Mild = 6.0% Moderate = 2.6%
Night glare#	14.1% Mild = 5.1% Moderate = 5.4% Severe = 3.6%	15.5% Mild = 2.6% Moderate = 10.3% Severe = 2.6%	4.2% Mild = 2.5% Moderate = 1.7%	4.3% Mild = 1.7% Moderate = 0.9% Severe = 1.7%
Starburst#	8.1% Mild = 3.6% Moderate = 3.3% Severe = 1.2%	6.0% Mild = 3.4% Moderate = 2.6%	0.8% Mild = 0.8%	1.7% Mild = 1.7%
Night vision difficulty	3.3%	0.0%	0.0%	0.0%
Entoptic phenomena†	4.2%	1.7%	1.7%	1.7%
Image Quality				
Blurred/difficulty with vision	19.5% Overall = 3.3% Distance = 5.4% Intermediate = 11.1% Near = 2.4%	11.2% Overall = 0.9% Distance = 2.9% Intermediate = 6.9% Near = 1.7%	14.3% Overall = 4.2% Distance = 0.0% Intermediate = 0.8% Near = 9.2%	12.9% Overall = 2.6% Distance = 1.7% Intermediate = 0.9% Near = 7.8%
Cloudy/hazy/filmy/foggy vision	3.9%	2.6%	1.7%	2.6%
Decreased vision	3.9%	2.9%	1.7%	2.6%
Fluctuation in acuity	3.6%	2.6%	5.9%	2.6%

* Reported with incidence rates of 3.0% or higher for at least one lens group
† Includes reports of arcs of light, rings (not halos) in vision, lens shimmer, light reflection/streaks, etc.
# Some subjects reported more than one visual disturbance. Reports of severe halos, night glare or starbursts were noted for 11.7% (39/333) of first eyes and 11.5% (34/296) of second eyes at 4-6 months. At one year, reports of severe halos, night glare or starbursts were noted for 6.9% (8/116) of both first and second eyes.

Directed subject responses for optical/visual symptoms were also obtained from a sponsor-developed questionnaire administered by a third-party over the telephone in which bilaterally implanted subjects were asked to rate their degree of "difficulty" for specific visual disturbances. It should be noted that directed questionnaires may contain inherent over-reporting as directed questioning is more subjective and is designed to elicit responses whether or not these would be deemed by the subject significant enough to voluntarily discuss with the investigator and study staff (non-directed response). Nonetheless, when specifically asked, statistically significant differences ($p<0.0001$[a]) were found between the two lens groups with more difficulty experienced with night vision, glare/flare and halos for multifocal subjects compared to monofocal subjects (**Table 24**). Although more difficulty was noted with the multifocal lens with respect to nighttime visual symptoms, overall levels of subject satisfaction remained high (95% or more would choose the same lens again when asked one year postoperatively) and exceeded that of the monofocal lens (as shown in **Table 19**). With respect to other optical/visual symptoms, subject questionnaire results also yielded some statistically significant differences between groups for

[a] P-value was not adjusted for multiplicity.

distorted near vision, distorted distance vision and blurred distance vision; however, the large majority of subjects in both lens groups reported no difficulty with these symptoms.

Table 24
Degree of Difficulty* Experienced with Visual Symptoms Without Glasses†
As Reported by Bilateral Subjects to a Prompted Choice Questionnaire
at 4-6 Months and One Year**

	Tecnis ZM900		Monofocal Control	
Question	4-6 Months N = 292	One Year N =112	4-6 Months N=118	One Year N =115
Night Vision				
No Difficulty	44.3%	50.0%	70.4%	77.4%
Moderate Difficulty	43.6%	42.0%	27.0%	20.9%
Severe Difficulty	12.1%	8.0%	2.6%	1.7%
Glare/Flare				
No Difficulty	33.6%	40.2%	59.0%	72.2%
Moderate Difficulty	41.4%	37.5%	34.2%	24.3%
Severe Difficulty	25.0%	22.3%	6.8%	3.5%
Halos				
No Difficulty	30.1%	42.0%	77.8%	80.0%
Moderate Difficulty	34.6%	31.3%	14.5%	15.7%
Severe Difficulty	35.3%	26.8%	7.7%	4.3%

* Scale: No difficulty = score of 1 or 2, Moderate difficulty = score of 3, 4 or 5, Severe difficulty = score of 6 or 7
† For items with statistically significant ($p<0.0001$) distributions between lens groups.

** Note: Although more difficulty was noted (during third-party administered questionnaires) with the multifocal lens with respect to nighttime visual symptoms, overall levels of subject satisfaction remained high (95% or more would choose the same lens again when asked one year postoperatively) and exceeded that of the monofocal lens (please refer to **Table 19**).

CLINICAL STUDY RESULTS for the Sensar® Monofocal Lens, Model AR40

The soft acrylic optic material was clinically studied in the US clinical trial of the monofocal Sensar® acrylic lens Model AR40, conducted between July 1996 and May 1998. The incidences of complications experienced during the clinical trial (**Table 25**) were comparable to or less than those of the historic control (FDA Grid) population. In the clinical study, there were 382 subjects implanted monocularly and the overall incidence of reported adverse events was 1.6%.

Table 25
Adverse Events – Sensar Monofocal Lens, Model AR40
All Subjects (N=382)

Adverse Events	Cumulative		Persistent at One Year		FDA Grid	
	N	%	N	%	Cum† (%)	Per†† (%)
Subjects with No Adverse Events	376	98.4	335	100.0	-	-
Subjects with Adverse Events*	6	1.6	0	0.0	-	-
- Corneal Edema	-	-	0	0.0	-	0.6
- Iritis	-	-	0	0.0	-	1.0
- Hyphema	0	0.0	-	-	1.0	-
- Macular Edema	3	0.8	0	0.0	3.5	0.8
- Pupillary Block	0	0.0	-	-	0.3	-
- Raised IOP Requiring Treatment	-	-	0	0.0	-	0.5
- Cyclitic Membrane	0	0.0	0	0.0	0.0	0.1
- Vitritis	-	-	0	0.0	-	0.1
- Endophthalmitis	1	0.3∞	-	-	<0.1	-
- Anterior Lens Tissue Ongrowth**	33	8.6	17	5.0	-	-
- Retinal Detachment	0	0.0	-	-	0.5	-
- Lens Dislocation	1	0.3	-	-	0.4	-
- Hypopyon	1	0.3	-	-	0.4	-
- Acute Corneal Decompensation	0	0.0	0	0.0	0.2	-
- Intraocular Infection	0	0.0	0	0.0	0.1	-
- Secondary Surgical Intervention (lens removal and replacement)	1	0.3	-	-	2.0	-

* One subject had both endophthalmitis and hypopyon.
† Cumulative incidence at one year visit.
†† Persistent incidence at one year visit.
∞ Incidence of endophthalmitis was not statistically different from the FDA grid.
** At the conclusion of the three-year clinical study, the cumulative and persistent incidences were 11.3% (43/382) and 7.4% (19/256) respectively; these incidences were not statistically different from the one-year levels. Of the 17 cases reported at one year, 8 cases resolved; 10 new cases of ongrowth were seen at the year three visit. Adverse effect on these subjects' vision was not reported by the investigators. Tissue ongrowth has been previously reported in the literature on other IOL material types.

DETAILED DEVICE DESCRIPTION: The Tecnis® multifocal lens is a three-piece foldable posterior chamber lens. The optic is made of hydrophobic soft acrylic and the haptics are made of polymethylmethacrylate (PMMA). This lens has a diffractive multifocal surface on the posterior side of the lens and a modified prolate (aspheric) surface on the anterior side. The optic is 6.0 mm in diameter and the lens has an overall diameter of 13.0 mm. The add power is +4 diopters, corresponding to +3 diopters in the spectacle plane.

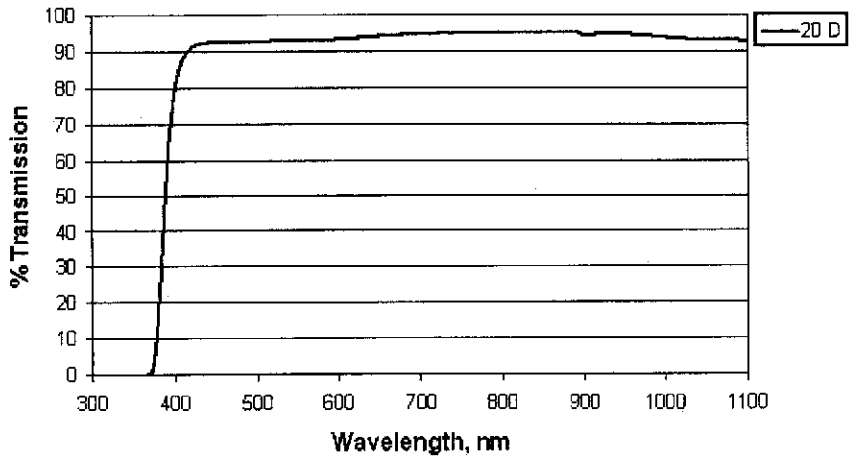
Lens Optic:
- Material: hydrophobic soft acrylic with a covalently bound UV absorber
- UV transmittance: for a typical 10 D lens, UV cut-off at 10% T is 379 nm; for a typical 30 D lens, UV cut-off at 10% T is 383 nm
- Index of refraction: 1.47 at 35°C
- Diopter power: 5.0 D to 34.0 D in 0.5 D increments.

Haptics:
- Material: Blue core polymethylmethacrylate (PMMA) monofilament

Dimensions (i.e., overall diameter, optic diameter, etc.) and loop shape of specific lens model is provided on the outside of the lens box.

Spectral transmittance testing of the acrylic material demonstrates that the UV cutoff wavelength (10% T) occurs at ~380 nm and the percent transmission at 600 nm (representing visible light transmission) is at least 90%. **Figure 8** shows the representative transmission spectra of a 20 D acrylic lens.

Figure 8: Percent Transmission Spectra for 20 D Acrylic Lens



DIRECTIONS FOR USE:

1. Prior to implanting, examine the lens package for proper lens model, dioptric power, and expiration date.
2. Open the package and remove the lens in a sterile environment.
3. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
4. The lens may be soaked in sterile balanced salt solution until ready for implantation.
5. The physician should consider the following points:
   - The surgeon should target **emmetropia** as this lens is designed for optimum visual performance when emmetropia is achieved.
   - Care should be taken to achieve **centration** of the intraocular lens.
6. AMO recommends using The UNFOLDER™ Emerald Series Insertion System (handpiece Model EmeraldT or EmeraldXL and cartridge Model EmeraldC) to insert the acrylic Tecnis® multifocal lens. Only insertion systems that have been validated and approved for use with this lens should be used.

CAUTION: Do not use the lens if the package has been damaged. The sterility of the lens may have been compromised.

LENS POWER CALCULATIONS: The physician should determine preoperatively the power of the lens to be implanted. **Emmetropia should be targeted.** The estimated A-constant for this lens is provided on the lens box; adjustments may be necessary if using IOLMaster. Accuracy of IOL power calculation is particularly important with multifocal IOLs as spectacle independence is the goal of multifocal IOL implantation.

Physicians requiring additional information on lens power calculations may contact the local AMO representative. Lens power calculation methods are described in following references:

- Holladay JT, Musgrove KH, Prager TC, Lewis JW, Chandler TY and Ruiz RS. A three-part system for refining intraocular lens power calculations. J Cataract Refract Surg. 19:17-24 1988.
- Retzlaff JA, Sanders DR and Kraff MC. Development of the SRK/T intraocular lens implant power calculation formula. J. Cataract Refract Surg. 16:333-340, 1990; ERRATA, 16:528, 1990.
- Olsen T, Olesen H, Thim K and Corydon L. Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas. J. Cataract Refract Surg. 18:280-285, 1992.
- Hoffer KJ. The Hoffer Q formula: A comparison of theoretic and regression formulas. J Cataract Refract Surg. 19:700-712, 1993; ERRATA 20:677, 1994.
- Holladay JT. Standardizing constants for ultrasonic biometry, keratometry and intraocular lens power calculations. J Cataract Refract Surg. 23-1356-1370, 1997.
- Norrby NES. Unfortunate discrepancies. Letter to the editor and reply by Holladay JT. J Cataract Refract Surg. 24:433-434, 1998.
- Norrby S, Lydahl E, Koranyi G, Taube M. Reduction of trend errors in power calculation by linear transformation of measured axial lengths. J Cataract Refract Surg 2003; 29:100-105
- http://www.augenklinik.uni-wuerzburg.de/eulib/index/htm is in particular useful for Zeiss IOLMaster users.

PATIENT CARD: An implant identification card, to be supplied to the patient, is included in the package. The patient should be instructed to keep the card as a permanent record of his/her implant and to show the card to any eye care practitioner he/she may see in the future.

REPORTING: Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity or rate of occurrence must be reported to AMO. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation.

Physicians are required to report these events in order to aid in identifying emerging or potential problems with posterior chamber lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term problems associated with these lenses or with intraocular lenses in general.

HOW SUPPLIED: Each Tecnis® multifocal foldable acrylic posterior chamber intraocular lens is supplied sterile, in dry form, in a lens container sealed within a single sterile pouch. The package is sterilized using ethylene oxide and should be opened only under sterile conditions.

EXPIRATION DATE: The expiration date on the lens package is the sterility expiration date. The lens should not be implanted after the indicated sterility expiration date.

RETURN/EXCHANGE POLICY: Contact the local AMO representative for the return lens policy. Return lens with proper identification and the reason for the return. Label the return as a biohazard.

Do not attempt to resterilize the lens.

Symbol/Explanation

SYMBOL	EXPLANATION
STERILE EO	Sterilized by Ethylene Oxide
②	Do Not Reuse
	Use By (YYYY-MM: Year-Month)
⚠	Caution; See Instructions for Use

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OptiEdge™ is produced and/or sold under at least one of the following U.S. letters: 6,162,249 and 6,468,306.

Manufactured by: AMO Groningen BV, 9728 NX Groningen, The Netherlands for Advanced Medical Optics, Inc., Santa Ana, CA, USA.
The CE marked IOLs comply with the European Council Directive 93/42/EEC of June 14, 1993.